

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Pasternak et al.
U.S. Serial No. : To Be Assigned
Filing Date : Herewith
For : TOPICAL ANESTHETIC/OPIOID
FORMULATIONS AND USES THEREOF
Group Art Unit : To Be Assigned

745 Fifth Avenue
New York, NY 10151

EXPRESS MAIL

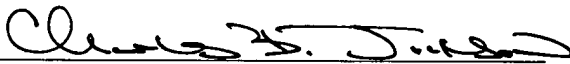
Mailing Label Number: EV 287825485 US

Date of Deposit: April 13, 2004

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on the date indicated above and is addressed to: **Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Charles B. Jackson

(Typed or printed name of person mailing paper or fee)



(Signature of person mailing paper or fee)

INFORMATION DISCLOSURE STATEMENT

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The Examiner's attention is respectfully drawn to the documents listed on the accompanying PTO form 1449. A copy of these documents was previously submitted to or cited by the USPTO in predecessor application Serial No. 09/975,812, filed October 11, 2001. Accordingly, no copy of these documents is submitted herewith.

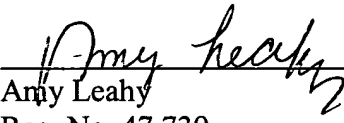
As this Information Disclosure Statement is being filed before the mailing of the first Office Action, it is believed that no fee is required for entry of this paper. However, the Commissioner is hereby authorized to charge any such fee, or credit any overpayment to Deposit Account 50-0320.

The filing of this Information Disclosure Statement is not an admission that the documents identified herein constitute prior art to the present application.

Applicants respectfully request that the Examiner considers and makes of record the documents cited herewith and that a copy of Form PTO-1449 be initialed by the Examiner and returned to the undersigned.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants



Amy Leahy
Reg. No. 47,739
(212) 588-0800

Encs. PTO Form 1449

Based on Form PTO-1449 (3/90) LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)	ATTY. DOCKET NO.	SERIAL NO.
	830010-2002.3	To Be Assigned
	APPLICANT	
	Pasternak et al.	
	FILING DATE	GROUP
	Herewith	To Be Assigned

U.S. PATENT DOCUMENTS							
-----------------------	--	--	--	--	--	--	--

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,866,143	02/02/99	Elkhoury			
	AB	5,654,281	08/05/97	Mayer, et al.			
	AC	5,523,323	06/04/96	Maccacchini			
	AD	5,321,012	06/14/94	Mayer, et al.			
	AE	5,689,489	11/18/97	Shin			
	AF	5,840,731	11/24/98	Mayer, et al.			
	AG	5,869,498	02/09/99	Mayer, et al.			
	AH	5,589,480	12/31/96	Elkhoury, et al.			
	AI	5,834,480	11/10/98	Elkhoury			
	AJ	4,626,539	12/02/86	Aungst, et al.			
	AK	5,635,204	06/03/97	Gevirtz, et al.			

FOREIGN PATENT DOCUMENTS								
--------------------------	--	--	--	--	--	--	--	--

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AL	WO 97/10815	03/27/97	WIPO				
	AM	WO 94/14427	07/07/94	WIPO				
	AN	WO 98/31358	07/23/98	WIPO				
	AO	WO 98/14427	04/09/98	WIPO				
	AP	WO 98/26770	6/25/98	WIPO				

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)			
--	--	--	--

	AQ	Adams et al. (1993) J. Pharmacol. Exp. Ther. 266(3): 1261-1267
	AR	Atanassoff et al (1997) Anesth. Analg. 84: 1340-1343
	AS	Butterworth and Strichartz (1990) Anesthesiol. 72: 711-734
	AT	Bliss & Collingridge (1993) Nature 361: 31-39
	AU	Catterall (1992) Science 242: 50-61
	AV	Catterall and Mackie (1996) Goodman & Gilman's, The pharmacologic basis of therapeutics, Ninth Edition (Hardman et al eds.) McGraw-Hill pp.331-347

EXAMINER	DATE CONSIDERED
----------	-----------------

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Based on Form PTO-1449 (3/90)				ATTY. DOCKET NO. 830010-2002.3		SERIAL NO. To Be Assigned		
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT Pasternak et al.				
				FILING DATE Herewith		GROUP To Be Assigned		
U.S. PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	AW	4,446,140	05/01/84	Nelson				
	AX	5,686,112	11/11/97	Liedtke				
	AY	6,191,126	02/20/01	Gamache				
	AZ	6,383,511	05/07/02	Cassel				
	BA	5,948,389	09/07/99	Stein				
	BB							
	BC							
	BD							
	BE							
FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	BF	WO 00/03716	01/27/00	WIPO				
	BG	JP 2000-169378	06/20/00	Japan (Abstract)				
	BH							
	BI							
	BJ							
	BK							
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)								
	BL		Courtney and Strichartz (1987) Handbook of Experimental Pharmacology, vol. 81. (Strichartz ed.) Springer-Verlag pp. 53-94					
	BM		Chen et al (1993) Mol. Pharmacol. 44: 8-12					
	BN		Hanson (1995) Remington: The Science and Practice of Pharmacy, 17 th edition, Mack Publishing Company p. 1146-1153					
	BO		Elliot et al. (1994) Pain 56: 69-75					
	BP		He and Lee (1998) J. Pharmacol. Exp. Ther. 285: 1181-1186					
	BQ		Horan et al. (1992) Life Sci. 50: 1535-1541					
EXAMINER				DATE CONSIDERED				
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

Based on Form PTO-1449 (3/90)				ATTY. DOCKET NO. 830010-2002.3		SERIAL NO. To Be Assigned	
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT Pasternak et al.			
				FILING DATE Herewith		GROUP To Be Assigned	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BR						
	BS						
	BT						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	BU						
	BV						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	BW		Kolesnikov and Pasternak (1999) J. Pharmacol. Exp. Ther. 290(1): 247-252				
	BX		Kolesnikov et al. (1996) Eur. J. Pharmacol. 310: 141-143				
	BY		Kolesnikov et al. (1996) J. Pharmacol. Exp. Ther. 279(2): 502-506				
	BZ		Kolesnikov et al. (1994) Life Sci. 55: 1393-1398				
	CA		Kolesnikov et al. (1993) Proc. Natl. Acad. Sci. USA 90: 5162-5166				
	CB		Kolesnikov Y.A. et al. "Peripheral blockade of topical morphine tolerance by ketamine" European Journal of Pharmacology, 1999, 374/2				
	CC		Lutz and Pfister (1992) J. Receptor Res. 12: 267-286				
	CD		Olson et al. (1989) Peptides 10: 1253-1280				
	CE		Pasternak (1993) Clin. Neuropharmacol. 16(1): 1-18				
	CF		Portoghese et al. (1992) Eur. J. Pharmacol. 218: 195-196				
	CG		Reisine and Pasternak (1996) Goodman & Gilman's, The pharmacological basis of Therapeutics, Ninth Edition (Hardman et al. Eds.) McGraw-Hill pp. 521-555				
	CH		Rossi et al (1994) Brain Res. 665: 85-93				
	CI		Saito et al. (1998) Anesthesiol. 89: 1455-1463				
	CJ		Saito et al (1998) Anesthesiol 89: 1464-1470				
	CK		Sibinga et al. (1998) Annu. Rev. Immunol. 6: 219-249				
	CL		Simon (1991) Medicinal res. Rev. 11: 357-374				
EXAMINER				DATE CONSIDERED			
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Based on Form PTO-1449 (3/90)				ATTY. DOCKET NO. 830010-2002.3		SERIAL NO. To Be Assigned	
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT Pasternak et al.			
				FILING DATE Herewith		GROUP To Be Assigned	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	CM						
	CN						
	CO						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	CP						
	CQ						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	CR		Sofuoglu et al. (1991) J. Pharmacol. Ther. 257(2): 676-680				
	CS		Standifer and Pasternak (1997) Cell Signal. 9, (No. ¼): 237-248				
	CT		Standifer et al. (1996) Mol. Pharmacol. 50: 293-298				
	CU		Trujillo and Akil (1991) Science 251: 85-86				
	CV		Yasuda et al (1993) Proc. Natl. Acad.Sci. USA 90: 6736-6740				
	CW		Yeung and Rudy (1980) J. Pharmacol. Exp. Ther. 215(3): 633-642				
	CX		Kolesnikov Yuri A et al. "Analgesic synergy between topical lidocaine and topical opioids" Journal of Pharmacology and Experimental Therapeutics, vo. 295, no. 2, November 2000 (2000-11) pages 546-551, XP 001080389				
	CY		Khouri G F et al. "Intraarticular Morphine, Bupivacaine, and Morphine/Bupivacaine for pain control after knee videoarthroscopy" Anesthesiology, American Society of Anesthesiologists, Philadelphia, PA, US, vol. 77, no. 263, 1992, pages 263-266, XP000910063				
	CZ		Kaneke Megumi et al. "Synergistic antinociceptive interaction after epidural coadministration of morphine and lidocaine in rats." Anesthesiology, vol. 80, no. 1, 1994, pages 137-150, XP001080405				
	DA		Saito Yoji et al. "Interaction of intrathecally infused morphine and lidocaine in rats (Part 1)." Anesthesiology (Hagerstown), vol. 89, no. 6, December 1998 (1998-12) pages 1455-1463, XP001080402				
	DB		Atanasoff Peter G et al. "The effect of intradermal administration of lidocaine and morphine on the response to thermal stimulation." Anesthesia & Analgesia, vol. 84, no. 6, 1997, pages 1340-1343, XP001079098				
	DC		Roy et al. " Transdermal Delivery of Narcotic Analgesics: Comparative Metabolism and Permeability of Human Cadaver Skin and Hairless Mouse Skin" Journal of Pharmaceutical Sciences, vol. 83 (12) December 1994, pages 1723-1728.				
	DD		Roy et al. "Transdermal Delivery of Narcotic Analgesics: Comparative Permeabilities of Narcotic Analgesics Through Human Cadaver Skin", Pharmaceutical Research, vol. 6(10) 1989, pages 825-832.				
	DE		Picard et al, "Analgesic efficacy of peripheral opioids (all except intra-articular): a qualitative systematic review of randomized controlled trials" Pain , Sept72(3) 1997, 309-318				
EXAMINER				DATE CONSIDERED			
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Based on Form PTO-1449 (3/90)				ATTY. DOCKET NO. 830010-2002.3		SERIAL NO. To Be Assigned	
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT Pasternak et al.			
				FILING DATE Herewith		GROUP To Be Assigned	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	DF						
	DG						
	DH						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	DI						
	DJ						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	DK		Moore et al. "The efficacy of locally applied morphine in post-operative pain after bilateral third molar surgery." Br J Clin Pharmacol 1994 Mar 37(3):227-30				
	DL		Leopold et al. "Percutaneous Penetration of Local Anesthetic Bases: Pharmacodynamic Measurements" The Journal of Investigative Dermatology, vol 113(3), September 1999, pages 304-307				
	DM		Saito et al. "Interaction of Intrathecally Infused Morphine and Lidocaine in Rats (Part 1), Anesthesiology, vol. 89, 1988, pages 1455-63				
	DN		Raja et al. "Comparison of postoperative analgesic effects of intraarticular bupivacaine and morphine following arthroscopic knee surgery." Anesthesiology 1992, Dec. 77(6): pages 1143-7.				
	DO		Rosseland et al. "Intra-articular morphine for pain relief after knee arthroscopy" Acta Anaesthesiol Scand 1999 Mar 43(3): 252-7.				
	DP		Fletcher et al. "Additivity of bupivacaine and morphine for peripheral analgesia in rats." Fundam Clin Pharmacol. 2000 July-Aug: 14(4), pages 327-34				
	DQ		Yarussi et al. "Evaluation of peripheral morphine analgesia for lumpectomy and axillary node dissection: a randomized, double-blind, placebo-controlled study." Reg. Anesth Pain Med 1999, Mar-Apr: 24(2), pages 142-145.				
	DR		Rosenstock et al. "Analgesic effect of incisional morphine following inguinal herniotomy under spinal anesthesia" Reg Anesth 1996 Mar-Apr, 21(2), pages 93-98.				
	DS		Merriam-Webster's Collegiate Dictionary. 10 th ed. (1999), "potentiate" page 912, Merriam-Webster, Incorporated.				
	DT						
	DU						
	DV						
	DW						
	DX						
EXAMINER				DATE CONSIDERED			
<p>* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>							